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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,990	12/27/2001	David Botstein	P2930R1C11	9535

9157 7590 03/01/2005

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EXAMINER	
FREDMAN, JEFFREY NORMAN	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,990	BOTSTEIN ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 22-41 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) 27-34 is/are allowed.

6)☒ Claim(s) 22-26 and 35-41 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/21/03; 4/29/03
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112 – Written Description

1. Claims 22-26 and 35-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number'' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

All of the current claims encompass a genus of nucleic acids which are different from those disclosed in the specification, since the claims are not limited to nucleic acids encoding SEQ ID NO: 9, but comprise variants with 80% to 99% sequence identity to SEQ ID NO: 9. Due to the "encoding" language, the variation from the single nucleic acid species actually disclosed, SEQ ID NO: 8, is even greater. This is due to the fact that the encoding language permits the use of alternative nucleic acid triplets which encode the same amino acid. The "encoding" language alone permits somewhere from 30 to 40 percent variation alone. That, in concert with the additional

variation permitted by the 80% identity language, makes this genus incorporate a variety of nucleic acids which are not described by the specification. In the context of the written description guidelines, examples 9 and 14 provide the closest fit to the current fact pattern. In example 9, a nucleic acid is claimed with a "wherein" clause which requires specific functionality from the proteins encoded by the nucleic acid. In example 14, a protein is claimed with percent identity language and an enzymatic function is recited. The current claims do not meet the standard imposed by examples 9 and 14 because the claims lack two elements found in the example. The claims lack any recited function whatsoever for the protein. Example 14 permits the use of the percent identity language because the function of the protein constrains the variations in the immense and undefined genus. In this case, where there is no function which so constrains the genus, the PRO982 nucleic acid is not described.

Significantly, the genus includes variants for which no written description is provided in the specification. This large genus is represented in the specification by only the particularly named SEQ ID No 8. Thus, applicant has express possession of only one particular sequence in a genus which comprises hundreds of millions of different possibilities. No common element or attributes of the sequences are disclosed, not even the presence of certain domains. In fact, the sequence has more than 80% identity in part to a chimpanzee sequence as shown below.

```
gi|55649452|ref|XM_512766.1|   PREDICTED: Pan troglodytes LOC456148
(LOC456148), mRNA
          Length = 528
Score =  159 bits (80), Expect = 1e-35
 Identities = 152/176 (86%)
 Strand = Plus / Plus
```

```
Query: 115 tggctcaggactgtggctgtgccagccgacacccaggtgtgggaacaagatctacaaccc 174
           ||||||||  ||  ||||||||||||||| ||||||||||||  ||||||||||||||||
Sbjct: 57  tggctcagaaccatggctgtgccagccggcacccaggtgtggagacaagatctacaaccc 116

Query: 175 ttcagagcagtgctgttatgatgatgccatcttatccttaaaggagacccgccgctgtgg 234
            |  |||||||||||||| |||||||||||  | ||| | |  ||||||||||  |||||
Sbjct: 117 cttggagcagtgctgttacgatgatgccatcgtgtccctgagcgagacccgccaatgtgg 176

Query: 235 ctccacctgcaccttctggccctgctttgagctctgctgtcccgagtcttttggcc 290
             ||  |||||||||||||||||||||||||||||||||||||| ||||| |||||||
Sbjct: 177 tccccactgcaccttctggccctgctttgagctctgctgtcctgagtcctttggcc 232
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There is no showing or evidence which links structural limitations or requirements to any particular functional limitations. Further, these claims encompass alternately spliced versions of the proteins, allelic variants including insertions and mutations, inactive precursor proteins which have a removable amino terminal end, and only specific nucleic and amino acid sequences have been provided. No written description of alleles, of upstream or downstream regions containing additional sequence, or of alternative splice variants has been provided in the specification.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

> "A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants

> hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

The current situation is a definition of the compound without identifying the structure function relationship of the compound, so that the compound is claimed solely by a sequence identity to SEQ ID NO: 8 without any functional limitation whatsoever.

In the instant application, an SEQ ID Nos 8 and 9 are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids other than those expressly disclosed which comprise sequences that share 80% to 99% sequence identity with SEQ ID NO 9 or which are SEQ ID NO: 9. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan et al (U.S. Patent 5,474,796).

Brennan teaches the formation of an array which comprises every single 10-mer (see column 9, lines 53-55). This complete set of 10-mers necessarily and inherently comprises all of the 10-mers of claims 35-37 and would inherently hybridize to SEQ ID NO 8 and nucleic acids which encode SEQ ID NO: 9.

Allowable Subject Matter

4. Claims 27-34 are allowed.

5. The following is a statement of reasons for the indication of allowable subject matter: The application expressly shows that the polypeptide, PRO982, is a mitogen which can induce cell proliferation, thereby providing a utility for the polypeptide and associated antigen. The Sequence encoding Seq ID NO: 9 and SEQ ID NO 8 itself are novel and unobvious over the prior art. Therefore, these claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey Fredman
Primary Examiner
Art Unit 1637
1/29/05